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rdenison@environmentaldefense.org

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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, kdnitsch@dow.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Commercial Hydroxyethylpiperazine (CAS# 103-76-4)

(Submitted via Internet 6/22/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and kdnitsch@dow.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Commercial Hydroxyethylpiperazine (CAS# 103-76-4).

The Dow Chemical Company, in response to EPA's High Production Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposed testing to address SIDS elements required for commercial hydroxyethylpiperazine, also known as Commercial HEP. Commercial HEP is synthesized by reacting ethylene oxide and aqueous piperazine to form a mixture of piperazine, hydroxyethylpiperazine, dihydroxyethylpiperazine and water. It is used primarily in the synthesis of triethylenediamine, which is in turn used as a urethane catalyst, and is used to a lesser extent to scavenge acid gases from natural gas streams.

Commercial HEP is said by the sponsor to be distributed to a limited number of customers, and thus to meet the EPA definition of a closed system intermediate. Qualification as a closed system intermediate is an EPA decision, but we would point out that its uses require that Commercial HEP be shipped offsite to multiple customers in considerable quantities. The test plan states that exposure is limited to occupational exposure but fails to discuss methods of packaging and shipping or potential for human and/or environmental exposure as a result of "upset conditions". (We assume the term "upset conditions" is used to indicate release of this chemical in the course of its production, use or transport.)

Commercial HEP is a data-poor chemical, but its constituent chemicals have been subjects of appreciable testing. Data on physical/chemical properties are available for Commercial HEP as well as for each of its constituents. Computer estimations indicate that these chemicals have little potential to persist in the environment. Aquatic toxicity estimates indicate they have low toxicity to fish, but significant toxicity to algae, and they have been shown to be relatively toxic to daphnia. Studies with animals indicate they have low acute toxicity, but are irritating and sensitizing when placed on the skin.

Data described in the test plan are clear and concise and supported by extensive robust summaries for each of the constituent chemicals. We note, however, that the structural formulas of the constituents of Commercial HEP are not presented in either the test plan or the robust summaries. The robust summaries are presented in considerable detail, sometimes more detail than desirable. Many replicates of the same tests are frequently described for the same chemicals. An extreme example is the inclusion of six or eight determinations of the melting point of the same chemical.

Also, much of the IUCLID Dataset for piperazine is in what appears to be German. If this material is going to be used in an HPV submission, it should be translated into English. Further, other than serving to bulk up the robust summaries, it doesn't seem necessary or even worthwhile to include what appears to be a 150-page working draft of a risk assessment for piperazine in the current submission.

We do, however, agree with conclusion 5.3.3.1 of this risk assessment that states there is no need for additional study of the reproductive/developmental toxicity of piperazine. In fact we would extend this conclusion to Commercial HEP. The test plan recommends additional reproductive/developmental toxicity studies (OECD 421) of Commercial HEP using the dermal route of exposure. However, since reproductive/developmental studies are available for piperazine and Commercial HEP has been established to be both irritating and sensitizing when placed on the skin, we see no need to subject additional animals to this trauma when the outcome of these studies is already obvious.

In summary, this submission has a number of weaknesses. Commercial HEP may not meet the specifications for consideration as a closed system intermediate as proposed, but we will defer to EPA on this decision. The robust summaries are overly inclusive and the test plan recommends what we consider unnecessary testing of reproductive/developmental toxicity. Nevertheless, we consider this submission acceptable.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense